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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,997	07/03/2003	Chih-I Lin	LINC3176/EM	3391

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EXAMINER

MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

TAKA

Office Action Summary	Application No. 10/611,997	Applicant(s) LIN ET AL.	
	Examiner Michael G. Mendoza	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2005.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-15 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☐ Claim(s) _____ is/are allowed.
 6) ☒ Claim(s) 1-3 and 5-15 is/are rejected.
 7) ☐ Claim(s) _____ is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☒ None of:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

1. Applicant's arguments filed 24 May 2005 have been fully considered but they are not persuasive.

2. In response to applicant's argument that Kuslich does not suggest how to anchor a tissue to a bone using 62, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

3. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

4. In response to applicant's argument that the primary reference fails to teach the claim limitation in wherein the plurality of pores each have a diameter that is less than 0.1 mm. The specification fails to teach any criticality to the limitation of the pore size.

The specification only states that the pore size is less than 0.1 mm. Because there is no criticality to the pore size, the pore size would be a simple design choice. Kuslich teaches a generalization of the pore size (col. 7, lines. The size of the pores in the device of Kuslich depend on the material packed into the device. It would be obvious to use a smaller pore size; including the pore size as limited by claim 1, depending on the viscosity of the material packed into the device. A higher viscosity material would require a smaller pore size.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-3 and 5-15 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Human beings and/or human anatomy are not statutory subject matter and as such cannot be positively set forth as an element(s) of a claimed invention. The examiner suggested amending claim 1 to recite "wherein said implant is adapted to be inserted into the bone" and "said sutures are adapted to be fastened".

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1, 2, 5, 6, 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuslich 5549679.

9. Kuslich teaches an device for anchoring a tissue to a bone, the device comprising: an implant made of a flexible wall and provided with a holding portion 44 and an injection port 48 in communication with the holding portion, with the holding portion being enclosed by the flexible wall which is provided with a plurality of pores (see figures); one or more sutures fastened with the implant (fig. 19); a pasty medicine (col. 9, lines 55-60, and col. 10, lines 26-28) capable of solidification injected into the holding portion. It should be noted that Kuslich fails to teach wherein the plurality of pores has a diameter smaller than 0.1 mm. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the limitation as claimed, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

10. Kuslich teaches the device as defined in claim 1, wherein the flexible wall of the implant is of a one-layered construction (see figs.); wherein the sutures are fastened at one end with the implant (fig. 19); wherein the injection port of the implant is provided with a suture hole for holding the sutures (fig. 19); wherein the implant is provided with an imaging body of metal conductor or graphite (col. 7, lines 47-48); wherein the implant is integrally made of the flexible wall such that the implant takes the form of sac, bag, or ball (see figs.); an injection tool comprising a connection tube (figs. 30-36), a

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syringe formed of a barrel 90 and a plunger 96; and a sleeve receiving the connection tube and the implant (fig. 30).

11. Claims 3, 7, 8, 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eisermann et al. 6827743.

12. Kuslich teaches the device as defined in claim 1. It should be noted that Kuslich fails to teach wherein the flexible wall of the implant is of a laminated multi-layered construction.

13. Eisermann et al. teaches a device with a common multi-layered construction for aiding in bone growth. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the multiply layers of Eisermann et al. to encourage bone growth (col. 2, lines 34-47).

14. As to claims 7 and 8, Kuslich/Eisermann teaches wherein the pasty medicine is a mixture of liquid and bone cement (col. 9, lines 55-60, and col. 10, lines 26-28, '679); wherein the bone cement is selected from the group of gypsum, calcium sulfate, calcium phosphate, poly(methylmethacrylate) and hydroxyl apatite (col. 2, line 65-col. 3, line 4, '743).

15. As to claims 14 and 15, Kuslich/Eisermann teaches wherein the flexible wall of the implant is of a laminated multi-layered construction and each layer of the material contains the pores; and wherein the pored in each layer are offset from the pores in the adjacent layer (fig. 1(c)).

Conclusion

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (571) 272-4698. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-44963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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